General

Guideline Title

Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions.

Bibliographic Source(s)

American Academy of Dermatology Work Group, Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB, Gottlieb A, Koo JY, Lebwohl M, Leonardi CL, Lim HW, Van Voorhees AS, Beutner KR, Ryan C, Bhushan R. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011 Jul;65(1):137-74. [201 references] PubMed

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Level of evidence grades (I-III) and strength of recommendations (A-C) are defined at the end of the "Major Recommendations" field.

Note from the National Guideline Clearinghouse (NGC): This guideline is the sixth section of the American Academy of Dermatology (AAD) "Guidelines of care for the management of psoriasis and psoriatic arthritis." In the first five sections of the guidelines, the AAD presents evidence supporting the use of topical treatments, phototherapy, traditional systemic agents, and biological therapies for patients with psoriasis and psoriatic arthritis. In this sixth and final section of the Psoriasis Guidelines of Care, the AAD presents cases to illustrate how to practically use these guidelines in specific clinical scenarios. Please see the following for information about the specific therapies recommended, including any adverse effects and contraindications:

- Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies
- Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 4. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents
- Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 5. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy

Ustekinumab Recommendations

- Indications: moderate-severe psoriasis
- Dosing: 45 mg of ustekinumab at baseline, 4 wk, and every 12 wk in those <100 kg, and 90 mg of ustekinumab at same intervals for those >100 kg
- Short-term efficacy: 75% improvement from baseline in Psoriasis Area and Severity Index score (PASI-75) in 67% at 12 wk
- Long-term efficacy: PASI-75 maintained in 87% of patients at 52 wk who attained PASI-75 at wk 12
- Toxicities:
    - Occasional injection-site reactions
    - Rare reports of serious infections and malignancies including skin cancers
    - Rare reports of major adverse cardiovascular events
    - Single report of reversible posterior leukoencephalopathy
- Baseline monitoring: (similar to other biologic agents)
    - Purified protein derivative (PPD) is required
    - Liver function test (LFT), complete blood cell count (CBC), and hepatitis profile
- Ongoing monitoring:
    - Periodic history and physical examination recommended while on treatment
    - Yearly PPD, and consider periodic CBC and LFT
- Pregnancy category: B

Golimumab Recommendations

- Indications: moderate to severe psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis. Note, golimumab does not have indication for psoriasis
- Dosing: 50 mg every 4 wk subcutaneously
- Efficacy for psoriatic arthritis: American College of Rheumatology (ACR) 20 in 51% at wk 14
    - Efficacy for psoriasis: PASI-75 in 40% at wk 14 (based on psoriatic arthritis study)
- Toxicities:
    - Occasional injection-site reactions
    - Rare reports of serious infections and nonmelanoma along with systemic malignancies
    - Although there are rare reports of drug-induced reversible side effects including lupus without central nervous system or renal complications, cytopenias, multiple sclerosis, and exacerbation along with new-onset congestive heart failure with other 3 tumor necrosis factor (TNF) inhibitors, there have been no reports of these reactions with golimumab to date. However, golimumab is a TNF and it should be used cautiously.
- Baseline monitoring:
    - PPD is required
    - LFT and CBC
- Ongoing monitoring:
    - Yearly PPD and consider periodic CBC and LFT treatment
    - Consider yearly PPD, and periodic CBC and LFT
- Pregnancy category: B

Strength of Recommendations for Use of Ustekinumab and Golimumab

Agent	Strength of Recommendation	Level of Evidence	References
Ustekinumab*	A	I	Blauvelt, 2008; Wolk et al., 2009; Clark et al., 1999; Robinson, Korman, & Korman 2007
Golimumab **	A	I	Kurd & Gelfand, 2009

*Data from phase III psoriasis trials.

**Data from phase III psoriatic arthritis trials.

Definitions:

Level of Evidence

I. Good-quality patient-oriented evidence
II. Limited-quality patient-oriented evidence
III. Other evidence including consensus guidelines, opinion, or case studies

Grade of Recommendation

A. Recommendation based on consistent and good-quality patient-oriented evidence
B. Recommendation based on inconsistent and limited-quality patient-oriented evidence
C. Recommendation based on consensus, opinion, or case studies

Clinical Algorithm(s)

The following algorithms are provided in the original guideline document:

- Algorithm for treatment of patients with limited disease
- Algorithm for treatment of patients with palmoplantar disease
- Algorithm for treatment of patients with erythrodermic psoriasis
- Algorithm for treatment of pediatric psoriasis involving greater than 5% body surface area
- Algorithm for treatment of men with psoriasis involving greater than 5% body surface area
- Algorithm for treatment of women of childbearing potential with psoriasis involving greater than 5% body surface area
- Algorithm for treatment of women trying to become pregnant with psoriasis involving greater than 5% body surface area
- Algorithm for treatment of patients with psoriatic arthritis

Scope

Disease/Condition(s)

- Psoriasis
- Psoriatic arthritis

Guideline Category

Evaluation

Management

Risk Assessment

Treatment

Clinical Specialty

Allergy and Immunology

Dermatology

Family Practice

Internal Medicine

Pediatrics

Rheumatology

Intended Users

Physicians

Guideline Objective(s)

- To describe the approach to treating patients with psoriasis across the entire spectrum of disease from mild to moderate to severe, with and without psoriatic arthritis, based on the 5 prior published guidelines
- To present cases to illustrate how to practically use these guidelines in specific clinical scenarios

Target Population

Children and adults with psoriasis and psoriatic arthritis

Interventions and Practices Considered

1. Ustekinumab
2. Golimumab

Note: Specific recommendations for the following therapies can be found in the previous sections of this guideline (see the "Major Recommendations" field): other biologic agents, topical medications, phototherapy, photochemotherapy, and traditional systemic drugs.

Major Outcomes Considered

- Efficacy of treatments
- Adverse effects of treatments
- Drug interactions

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A work group of recognized psoriasis experts was convened to determine the scope and structure of this final guideline. An evidence-based model was used and evidence was obtained using a search of the PubMed/MEDLINE database spanning the years 1960 through 2010. Only English-language publications were reviewed.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Committee)

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Evidence was graded using a 3-point scale based on the quality of methodology as follows:

I. Good-quality patient-oriented evidence
II. Limited-quality patient-oriented evidence
III. Other evidence including consensus guidelines, opinion, or case studies

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

The available evidence was evaluated using a unified system called the Strength of Recommendation Taxonomy developed by editors of the United States (U.S.) family medicine and primary care journals (i.e., *American Family Physician, Family Medicine, Journal of Family Practice, and BMJ USA*). This strategy was supported by a decision of the Clinical Guidelines Task Force in 2005 with some minor modifications for a consistent approach to rating the strength of the evidence of scientific studies.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Clinical recommendations were developed on the best available evidence tabled in the guideline. In those situations where documented evidence-based data are not available, expert opinion was used to generate clinical recommendations. Prior guidelines on psoriasis were also evaluated.

Rating Scheme for the Strength of the Recommendations

A. Recommendation based on consistent and good quality patient-oriented evidence
B. Recommendation based on inconsistent or limited quality patient-oriented evidence
C. Recommendation based on consensus, opinion, or case studies

Cost Analysis

Published cost analyses were reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

These guidelines have been developed in accordance with the American Academy of Dermatology (AAD)/American Academy of Dermatology Association "Administrative Regulations for Evidence-Based Clinical Practice Guidelines," which include the opportunity for review and comment by the entire AAD membership, review and approval by the Clinical Guidelines and Research Committee, and final review and approval by the AAD Board of Directors.

Evidence Supporting the Recommendations

References Supporting the Recommendations

Blauvelt A. T-helper 17 cells in psoriatic plaques and additional genetic links between IL-23 and psoriasis. J Invest Dermatol. 2008 May;128(5):1064-7. [23 references] PubMed

Clark CM, Kirby B, Morris AD, Davison S, Zaki I, Emerson R, Saihan EM, Chalmers RJ, Barker JN, Allen BR, Griffiths CE. Combination treatment with methotrexate and cyclosporin for severe recalcitrant psoriasis. Br J Dermatol. 1999 Aug;141(2):279-82. PubMed

Kurd SK, Gelfand JM. The prevalence of previously diagnosed and undiagnosed psoriasis in US adults: results from NHANES 2003-2004. J Am Acad Dermatol. 2009 Feb;60(2):218-24. PubMed

Robinson MR, Korman BD, Korman NJ. Combination immunosuppressive therapies: the promise and the peril. Arch Dermatol. 2007 Aug;143(8):1053-7. [35 references] PubMed

Wolk K, Haugen HS, Xu W, Witte E, Waggie K, Anderson M, Vom Baur E, Witte K, Warszawska K, Philipp S, Johnson-Leger C, Volk HD, Sterry W, Sabat R. IL-22 and IL-20 are key mediators of the epidermal alterations in psoriasis while IL-17 and IFN-gamma are not. J Mol Med. 2009 May;87(5):523-36. PubMed

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for selected recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate treatment and management of psoriasis and psoriatic arthritis
- Avoidance of serious drug-drug interactions and drug toxicities

Potential Harms

Adverse Effects of Treatment

Ustekinumab

- Occasional injection-site reactions
- Rare reports of serious infections and malignancies including skin cancers
- Rare reports of major adverse cardiovascular events
- Single report of reversible posterior leukoencephalopathy

Golimumab

- Occasional injection-site reactions
- Rare reports of serious infections and nonmelanoma along with systemic malignancies
- Although there are rare reports of drug-induced reversible side effects including lupus without central nervous system or renal complications,

cytopenias, multiple sclerosis, and exacerbation along with new-onset congestive heart failure with the other 3 tumor necrosis factor (TNF) inhibitors, there have been no reports of these reactions with golimumab to date. However, golimumab is a TNF inhibitor and it should be used cautiously.

Note: See the original guideline document for discussions concerning general and specific safety issues of other medications used for the management of psoriasis and psoriatic arthritis. Also see the National Guideline Clearinghouse (NGC) summaries of the five previous sections of the "Guidelines of care for the management of psoriasis and psoriatic arthritis" for more specific information (see the "Major Recommendations" field).

Qualifying Statements

Qualifying Statements

Adherence to these guidelines will not ensure successful treatment in every situation. Furthermore, these guidelines should not be interpreted as setting a standard of care or deemed inclusive of all proper methods of care nor exclusive of other methods of care directed toward obtaining the same results. The ultimate judgment regarding the propriety of any specific therapy must be made by the physician and the patient in light of all the circumstances presented by the individual patient.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

Patient Resources

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

American Academy of Dermatology Work Group, Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB, Gottlieb A, Koo JY, Lebwohl M, Leonardi CL, Lim HW, Van Voorhees AS, Beutner KR, Ryan C, Bhushan R. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011 Jul;65(1):137-74. [201 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 Jul

Guideline Developer(s)

American Academy of Dermatology - Medical Specialty Society

Source(s) of Funding

American Academy of Dermatology operational funds and member volunteer time supported the development of this guideline.

Guideline Committee

Psoriasis Work Group

Composition of Group That Authored the Guideline

Work Group Members: Alan Menter, MD (*Chair*), Psoriasis Research Center, Baylor University Medical Center, Dallas; Neil J. Korman, MD, PhD, Murdough Family Center for Psoriasis, Department of Dermatology, University Hospitals Case Medical Center, Cleveland; Craig A. Elmets, MD, Department of Dermatology, University of Alabama at Birmingham; Steven R. Feldman, MD, PhD, Department of Dermatology, Wake Forest University School of Medicine, Winston-Salem; Joel M. Gelfand, MD, MSCE, Department of Dermatology and Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania, Philadelphia; Kenneth B. Gordon, MD, Division of Dermatology, Evanston Northwestern Healthcare and Department of Dermatology, Northwestern University, Feinberg School of Medicine, Chicago; Alice Gottlieb, MD, PhD, Tufts Medical Center, Tufts University School of Medicine, Boston; John Y. M. Koo, MD, Department of Dermatology, University of California - San Francisco; Mark Lebwohl, MD, Department of Dermatology, Mount Sinai School of Medicine, New York; Craig L. Leonardi, MD, Saint Louis University; Henry W. Lim, MD, Department of Dermatology, Henry Ford Hospital, Detroit; Abby S. Van Voorhees, MD, Department of Dermatology, University of Pennsylvania, Philadelphia; Karl R. Beutner, MD, PhD, Department of Dermatology, University of California, San Francisco, Anacor Pharmaceuticals Inc, Palo Alto; Caitriona Ryan, MB, BCh, BAO, Psoriasis Research Center, Baylor University Medical Center, Dallas; Reva Bhushan, PhD, American Academy of Dermatology, Schaumburg

Financial Disclosures/Conflicts of Interest

Alan Menter, MD, Chair, Psoriasis Work Group: Dr Menter served on the Advisory Board and was a consultant, investigator, and speaker for Abbott Labs, Amgen, and Centocor receiving grants and honoraria; was a consultant, investigator, and speaker for Wyeth receiving honoraria;

served on the Advisory Board and was an investigator and consultant for UCB receiving grants and honoraria; was a consultant, investigator, and speaker for Warner Chilcot and Wyeth receiving honoraria; served on the Advisory Board and was an investigator for Galderma and Genentech receiving grants and honoraria; was a consultant and investigator for Eli Lilly receiving grants and Astellas receiving grants and honoraria; was an investigator for Celgene, Ausbio, and Syntrix Biosystems receiving grants and Novo Nordisk receiving no compensation, and an investigator and speaker for Pfizer receiving grants and honoraria.

Neil J. Korman, MD, PhD: Dr Korman has served on the Advisory Board and was investigator and speaker for Genentech and Astellas receiving grants and honoraria; served on the Advisory Board and was investigator for Centocor receiving grants and residency/fellowship program funding; was investigator and speaker for Amgen receiving grants and honoraria; and served on the Advisory Board, was consultant, investigator, and speaker for Abbott Labs receiving grants and honoraria.

Craig A. Elmets, MD: Dr Elmets has served as an investigator for Abbott and Genentech receiving grants; was consultant for Astellas receiving honoraria; and was a consultant for ISDIN receiving other financial benefit.

Steven R. Feldman, MD, PhD: Dr Feldman served on the Advisory Board and was investigator and speaker for Galderma, Stiefel, Warner Chilcott, Abbott Labs, and Astellas receiving grants and honoraria; served on the Advisory Board for Photomedex receiving stock options; received grants from National Psoriasis Foundation and Dermatology Foundation, Coria, ASDS, Aventis Pharma Ortho Pharma, Pharmaderm, and Roche Dermatology; was an investigator and speaker for Amgen, Centocor, Connetics, and Genentech receiving grants and honoraria; was a speaker and consultant for Bristol-Myers Squibb Derm receiving grants; a speaker for Novartis and 3M receiving grants; and a consultant and speaker for Bristol-Myers Squibb Derm and Biogenidec receiving grants. He received separate department funding from Acuderm, Advanced Tissue Sciences, Allergan, Aventis, Bristol-Myers Squibb, Combe, Curatek, Ferndale, Fujisawa, Hermal, Hoffman LaRoche, Galderma, Genderm, Glaxo Wellcome, Hill, Janssen, Mayrand, Neostrata, Neutrogena, Novartis, Oclassen, Ortho, Person & Covey, Proctor & Gamble, RJR Nabisco, Schering-Plough, Shelton, SmithKline, Stiefel, 3M, United Catalyst, Upjohn and Wolff Systems.

Joel M. Gelfand, MD: Dr Gelfand served as consultant and investigator with Amgen, Centocor, Abbott, Pfizer, Novartis, and Genentech receiving grants and honoraria; was consultant with Wyeth, Shire Pharmaceuticals, Galderma, Celgene, UBC, and Merck receiving honoraria; and investigator with Shionogi and NIH receiving grants.

Kenneth B. Gordon, MD: Dr Gordon served on the Advisory Board and was consultant, investigator, and speaker for Abbott Labs and Amgen receiving grants and honoraria; was investigator for Celgene receiving grants and was on the Advisory Board, a consultant, and investigator for Centocor receiving grants and honoraria; and on the Advisory Board for Lilly, Pfizer receiving honoraria and on the Advisory Board and investigator for Merck receiving grants and honoraria.

Alice Gottlieb, MD, PhD: Dr Gottlieb served as a consultant, investigator, and on the Advisory Board for Amgen Inc, receiving grants and honoraria; a consultant and served on Advisory Board for Celgene receiving honoraria, served on Advisory Board for Actelion, Cytokine Pharmasciences, Pfizer, and UCB receiving honoraria, consultant for BIND Biosciences, Inc, Magen Biosciences, Schering, Canfite, Incyte, Merck, Ono, and Puretech receiving honoraria; investigator and Advisory board for NovoNordisk and Abbott and Centocor receiving grants and honoraria, and an investigator for Immune control receiving grants.

John Y. M. Koo, MD: Dr Koo served on the Advisory Board, was speaker, consultant and investigator for Amgen, Abbott Labs, Astellas, Warner Chilcott, and Galderma, receiving grants and honoraria; was investigator for Genentech receiving grants; and was on the Advisory Board, consultant and investigator for Photomedix and Teikoku, receiving no compensation.

Mark Lebwohl, MD: Dr Lebwohl served as consultant receiving honoraria for Abbott Laboratories, Allostera, Amgen/Pfizer, Astellas, Cambridge Pharma, Can-Fite Biopharma, Celgene, Centocor/Janssen/J&J, DermaGenoma, DermiPsor, GlaxoSmithKline-Stiefel, Norvartis, and Ranbaxy. Members of Dr Lebwohl's department own patents on short-contact tazarotene, topical genistein, and use of the excimer laser for vitiligo. Members of Dr. Lebwohl's department serve as investigators for numerous companies including: Abbott, Actavis, Amgen, aRigen, Astellas, Basilea, Bioform, Celgene, Centocor, Dusa, Galderma, Genentech, Graceway, Lumenis, Longport, Medicis, Novartis, NovoNordisk, Peplin, Pharmaderm, Provectus, Ranbaxy, Roche, Stiefel, and Wyeth. Dr Lebwohl is a course director for the annual Fall and Winter Clinical Dermatology Conferences and the annual Mount Sinai Winter Symposium which receive support from numerous dermatology companies.

Craig L. Leonardi, MD: Dr Leonardi served as investigator, speaker, and on the advisory Board for Abbott, Amgen, Centocor receiving honoraria and other financial benefit; investigator for Celgene, Eli Lilly, Galderma, Genentech, Glaxo Smith Kline, Novartis, Novo Nordisk, Sirtris, Stiefel, Vascular Biogenics, and Wyeth, receiving other financial benefit, served as investigator and on the Advisory Board for Pfizer receiving honoraria and other financial benefit, and as speaker and Advisory board for Centocor receiving honoraria.

Henry W. Lim, MD: Dr Lim is consultant receiving honoraria for LaRoche-Posay and Orfagen.

Abby S. Van Voorhees, MD: Dr Van Voorhees served on the Advisory Board, was an investigator and speaker and consultant for Amgen receiving grants and honoraria; advisory board member and speaker for Abbott, Connetics, Centocor receiving honoraria; Advisory board, speaker, and investigator for Genentech receiving honoraria and grants; consultant for Incyte, VGX, Leo, and Xtrac receiving honoraria, advisory board and investigator for Warner Chilcott, Bristol-Myers Squibb receiving grants and honoraria; Investigator for Roche, Astellas, IDEC receiving grants; and served another role for Synta receiving honoraria. Dr Van Voorhees' husband is an employee of Merck, receiving salary, stock, and stock options.

Karl R. Beutner, MD, PhD, Chair Clinical Research Committee: Dr Beutner was consultant for Anacor receiving honoraria, stock and stock options.

Caitriona Ryan, MD: Dr Ryan was a speaker for Jansen-Cilag receiving honoraria, served on the advisory board for Galderma receiving honoraria, and had another role with Abbott receiving grants.

Reva Bhushan, PhD: Dr Bhushan had no relevant conflicts of interest to disclose.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from American Academy of Dermatology Association Web site .

Print copies: Available from the AAD, PO Box 4014, Schaumburg, IL 60168-4014, Phone: (847) 330-0230 ext. 333; Fax: (847) 240-1859; Web site: www.aad.org.

Availability of Companion Documents

Case studies are presented throughout the original guideline document .

Patient Resources

The following is available:

- Psoriasis and psoriatic arthritis. Pamphlet. American Academy of Dermatology (AAD); 2010. Electronic copies: Available from the AAD Web site .

Print copies: Available for purchase from the Available from the AAD, PO Box 4014, Schaumburg, IL 60168-4014, Phone: (847) 330-0230; Fax: (847) 240-1859; Web site: www.aad.org .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

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